

97-047-HFS-RURAL MEDICAL
127 CENTER



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Department of Health and Family Services

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October 30, 1998

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The Honorable Brian Rude, President
Wisconsin State Senate
1 East Main, Suite 402
Madison, WI 53702

The Honorable Scott Jensen, Speaker
Wisconsin State Assembly
1 East Main, Suite 402
Madison, WI 53702

Re: Clearinghouse Rule 97-047
HFS 127, relating to the operation of rural medical centers.

Gentlemen:

In accordance with the provisions of s. 227.19(2), Stats., you are hereby notified that the above-mentioned rule is in final draft form. This notice and the report required by s. 227.19(3), Stats., are submitted herewith in triplicate.

The rule was submitted to the Legislative Council for review under s. 227.15, Stats. A copy of the Council's report is also enclosed.

If you have any questions about the rule, please contact Lillian Redding at 266-8482.

Sincerely,

Paul E. Menge
Administrative Rules Manager

cc. Gary Poulson, Deputy Revisor of Statutes
✓ Senator Robert Welch, JCRAR
Representative Glenn Grothman, JCRAR
Lillian Redding, Division of Supportive Living
Kevin Lewis, Secretary's Office

PROPOSED ADMINISTRATIVE RULES--HFS 127
ANALYSIS FOR LEGISLATIVE STANDING COMMITTEES
PURSUANT TO S. 227.19(3), STATS.

Need for Rules

Section 50.51, Stats., establishes a new type of electively licensed health care entity called a rural medical center. A rural medical center provides different kinds of inpatient and outpatient health care services tailored to community needs. It has a single governing body and corporate structure. It is located in a county, city, town or village with a population of not more than 15,000 and in a nonurbanized area as determined by the U.S. Bureau of Census. It offers two or more types of health care services that are subject to survey inspections by the Department to determine compliance with state and federal requirements. Types of services that could be provided by a rural medical center include hospital services, nursing home services, home health agency services, outpatient physical therapy services and ambulatory surgery center services.

Section 50.51, Stats., directs the Department to license, inspect and regulate rural medical centers on the basis of standards for their operation, promulgated as rules, that are designed to protect and promote the health, safety, rights and welfare of patients and residents receiving health care services from the centers. These are the proposed rules.

If an organization meets the statutory criteria for being a rural medical center, it may apply to the Department to be licensed as a rural medical center. To be licensed as a rural medical center, an organization must comply with the standards set out in these rules. These rules incorporate, by reference, Department rules and federal regulations that separately govern the services that a rural medical center may provide.

Being licensed as a rural medical center will be advantageous for a multi-service health care provider in rural Wisconsin for a number of reasons. These include: a single application process instead of two or more; consolidated fees; a single license; and consolidated surveys and inspections by the Department's Bureau of Quality Assurance.

Responses to Clearinghouse Recommendations

All comments of the Legislative Council's Rules Clearinghouse were accepted, except the following:

- 1.a. Comment: For rural medical centers, s. 50.50(6), Stats., provides that "hospital" has the meaning given in s. 50.33(2)(a) or (b), Stats., except that it does not include a rural primary care hospital. However, proposed HFS 127.02(10) has a broader definition. There is no statutory authority for a broader definition.

Response: The reference to s. 50.33(2), Stats., has been corrected by limiting it to pars. (a) and (b). The term rural primary care hospital has been eliminated because this federal program has ended.

- 5.k.(2) Comment: Although the rules at HFS 127.03(4)(d)6. (intro.) and c. permit the Department to determine whether there are convictions for certain criminal offenses in the background of any license applicant or center operator, there is no mechanism in the rules for conducting a criminal background

investigation. It is not clear how DHFS will obtain the necessary information to consider any convictions.

Response: The mechanism for criminal background checks is found in ch. HFS 12, which implements standard background information search requirements under s. 50.065, Stats., as created by 1997 Wisconsin Act 27. A reference to ch. HFS 12 has been added to HFS 127.03 (4)(d)6. (intro.)

5.o. Comment: In HFS 127.03(8)(d)2. it appears that a reference to "suspension" should also be included.

Response: The Department would not suspend the license of an entity that houses patients or residents, due to the resulting disruption. It would either revoke the license of the entity or impose an intermediate sanction that allows the entity to maintain operations. A license suspension is more appropriate for an entity that does not provide inpatient care.

5.p. Comment: In HFS 127.05(2)(b), the second-to-last occurrence of "or" should be replaced by a comma.

Response: No change. "Certification" goes with "facility" rather than "legally authorized function."

5.u. Comments: In HFS 127.08(2)(c) and (3)(a)1.d., the word "of" should be inserted before the word "management."

Response: That is not what is meant. To clarify, these provisions are re-phrased to read: "is in the interests of the management of patient or resident care."

Public Hearings

The Department held four public hearings on the proposed rules. The hearings were in Green Bay, Rhinelander, Eau Claire, and Reedsburg in May 1997. No one attended the hearings in Green Bay, Rhinelander and Eau Claire. One person attended the hearing in Reedsburg but did not testify. No written comments were received during the public review period that ended on May 23, 1997.

Following the hearings, the Department, on its own initiative, made three types of changes in the proposed rules, as follows:

The Department added clarifying language in three places in the rules under applying for an initial license. In HFS 127.03(2)(a)(8), the word "detailed" was added so that the required description of the service area is to be a "detailed description," and in HFS 127.03(2)(a)9. and HFS 127.03(2)(b)2. a requirement was added that the applicant furnish street addresses and indicate the distance of each service provider from the rural medical center building.

The Department deleted the obsolete term, "rural primary care hospital," used in connection with a former federal demonstration program. The Department also added the term "critical access hospital" as used in the newly enacted federal Medicare Rural Hospital Flexibility Program, and added a definition for it.

The Department deleted all references to license renewal. This is because 1997 Wisconsin Act 27, effective October 14, 1997, established "non-expiring" licenses for eight categories of health care facilities serving adults, including rural medical centers.

Final Regulatory Flexibility Analysis

These rules apply to health care facilities or programs in rural areas that operate under a single governing body to provide at least two types of health care services usually licensed or certified separately by the Department, and facilities that choose to be licensed and regulated as rural medical centers. A rural medical center could be a small business, as defined in s. 227.114(1)(a), Stats., but that is unlikely because of the numbers of staff a rural medical center would have.

These new rules will not add to the current facility or program reporting or record-keeping requirements, nor will compliance with them require professional skills that facilities and programs do not have now. The Department is simply promulgating rules for a new, elective licensure category established under subch. III of ch. 50 Stats., which is intended to ease the regulatory burden for eligible facilities and programs, for instance, by consolidating currently separate surveys.

PROPOSED ORDER OF THE
DEPARTMENT OF HEALTH AND FAMILY SERVICES
CREATING RULES

To create chapter HFS 127, relating to the operation of rural medical centers.

Analysis Prepared by the Department of Health and Family Services

A recent session law, 1995 Wisconsin Act 98, created subch. III of ch. 50, Stats., which establishes a new type of licensed health care entity called a rural medical center. A rural medical center provides different kinds of inpatient and outpatient health care services tailored to community needs. It has a single governing body and corporate structure. It is located in a county, city, town or village with a population of not more than 15,000 and in a nonurbanized area as determined by the U.S. Bureau of the Census. It offers two or more types of health care services that are subject to survey inspections by the Department to determine compliance with state and federal requirements. Types of services that could be provided by a rural medical center include hospital services, nursing home services, home health agency services, outpatient physical therapy services and ambulatory surgery center services.

Section 50.51, Stats., as created by Act 98, directs the Department to license, inspect and regulate rural medical centers on the basis of standards for their operation that are promulgated as rules and that are designed to protect and promote the health, safety, rights and welfare of patients and residents receiving health care services from the centers. These are the proposed rules.

If an organization meets the statutory criteria for being a rural medical center, it may apply to the Department to be licensed as a rural medical center. To be licensed as a rural medical center, an organization must comply with the standards set out in these rules. These rules incorporate by reference Department rules and federal regulations that separately govern the services that a rural medical center may provide.

The rules repeat and add greater specificity to the requirements of subch. III of ch. 50, Stats., as created by Act 98. They specify all of the following:

- types of health care services that rural medical centers may be licensed to provide;
- requirements for license applications and fee amounts based on the types of health care services to be provided;
- license application review criteria and inspection requirements for full review of new health care services and expedited review of existing health care services;
- procedures for issuance of regular licenses, as well as six-month provisional licenses for rural medical center applicants that have not previously been licensed by the Department or certified by the federal government to provide any of the proposed health care services;
- procedures for appealing a decision of the Department to deny issuance of a license or to suspend or revoke a license;

- requirements a for new license when there is a change in ownership;
- complaint investigation and survey inspection requirements, including access to financial, administrative and patient or resident health care records;
- requirement for consolidated facility surveys and inspections insofar as the health care services listed on the license can be surveyed or inspected at the same time and in an outcome-based, program-wide manner;
- violation, penalty and forfeiture requirements and appeal procedures;
- procedures for requesting a waiver or variance from a rule requirement and for appealing the denial of a request for a waiver or variance; and
- incorporation by reference of program and operational standards.

The types of health care services that a rural medical center may provide are hospital, critical access hospital, nursing home, hospice, home health, rural health clinic, ambulatory surgery center, outpatient physical therapy, outpatient occupational therapy, and end-stage renal disease services. The Department may in the future specify other services by rule. Combinations of health care services at a rural medical center could include, for example, a rural nursing home that also operates a home health agency or hospice program, or a rural hospital that also operates a nursing home.

Being licensed as a rural medical center will be advantageous for a multi-service health care provider in rural Wisconsin for a number of reasons. These include: a single application process, instead of two or more; consolidated fees; a single license; and consolidated surveys and inspection by the Department's Bureau of Quality Assurance.

The Department's authority to create these rules is found in s. 50.51(2), Stats. The rules interpret ss. 50.50 to 50.56, Stats.

SECTION 1. Chapter HFS 127 is created to read:

Chapter HFS 127

RURAL MEDICAL CENTERS

Subchapter I - General

- HFS 127.01 Authority, purpose and applicability
- HFS 127.02 Definitions
- HFS 127.03 Licensure
- HFS 127.04 Compliance with laws
- HFS 127.05 Inspections and investigations
- HFS 127.06 Consolidated survey requirement
- HFS 127.07 Violations and penalties
- HFS 127.08 Waivers and variances

Subchapter II - Program and Operational Standards

- HFS 127.16 Nursing home services
- HFS 127.17 Hospital services
- HFS 127.18 Home health services
- HFS 127.19 Hospice services
- HFS 127.20 Critical access hospital services
- HFS 127.21 Rural health clinic services
- HFS 127.22 Rehabilitation, outpatient physical therapy and outpatient occupational therapy services
- HFS 127.23 Ambulatory surgery center services
- HFS 127.24 End-stage renal disease services

SUBCHAPTER I - GENERAL

HFS 127.01 AUTHORITY, PURPOSE AND APPLICABILITY. (1) This chapter is promulgated under the authority of s. 50.51(2), Stats., to establish standards for the construction, maintenance and operation of rural medical centers for the purposes of:

- (a) Facilitating access to quality health care in rural communities.
- (b) Promoting the development of integrated health care services in rural communities in a manner that does all of the following:
 - 1. Promotes flexibility and ease of diversification in service delivery.
 - 2. Encourages efficient use of available health care resources.
 - 3. Encourages consistency of standards across types of care.

(2) This chapter applies to all entities that meet the definition of rural medical center in s. HFS 127.02(22) and apply to be licensed under this chapter.

HFS 127.02 DEFINITIONS. In this chapter:

(1) "Adverse action" means an action initiated by a state or federal agency, based on the licensee's noncompliance in the operation of health care services, that resulted in civil money penalties, suspension of payments, the appointment of temporary management, denial, suspension or revocation of licensure or termination or nonrenewal of provider participation under medicaid or medicare.

(2) "Ambulatory surgery center" has the meaning given in s. 49.45(6r)(a)1., Stats.

(3) "Applicant" means a person or persons who apply for a license to operate a rural medical center, who ultimately will be responsible for the operation of the rural medical center and legally responsible for decisions and liabilities related to the rural medical center. If a corporation, "applicant" means each person serving as director as indicated under ss. 180.0202(2)(a) and 181.31(1)(h), Stats. If a partnership, "applicant" means persons identified in s. 178.03(1), Stats. If a limited partnership, "applicant" means persons identified in ch. 179, Stats. If a limited liability company, "applicant" means each person organizing the company as identified under s. 183.0202(5), Stats.

(4) "Critical access hospital" has the meaning given in 50.33(1g), Stats.

(5) "Department" means the Wisconsin department of health and family services.

(6) "End-stage renal disease service" has the meaning given in 42 CFR 405.2102.

(7) "Good standing" means that the applicant has a history of compliance with state and federal statutes, regulations and rules that promote the provision of quality care to patients and residents.

(8) "Health care services" or "services" means any of the following:

(a) Care that is provided in or by any of the following:

1. A hospital.
2. A nursing home.
3. A hospice.
4. A rural health clinic.
5. An ambulatory surgery center.
6. A critical access hospital.

(b) Home health services.

(c) Outpatient physical therapy services.

- (d) End-stage renal disease services.
- (e) Services that are provided by a rehabilitation agency.
- (f) Outpatient occupational therapy services.
- (9) "Home health services" has the meaning given in s. 50.49(1)(b), Stats.
- (10) "Hospice" has the meaning given in s. 50.90(1), Stats.
- (11) "Hospital" has the meaning given in s. 50.33(2)(a) or (b), Stats.
- (12) "Medicare" means Title XVIII of the federal Social Security Act of 1935, as amended, 42 USC 1395 to 1395ccc.
- (13) "Nursing home" has the meaning given in s. 50.01(3), Stats.
- (14) "Outpatient occupational therapy services" has the meaning given in 42 USC 1395x(g).
- (15) "Outpatient physical therapy services" has the meaning given in 42 USC 1395x(p).
- (16) "Patient" means an individual who receives health care services, except nursing home services, from a rural medical center.
- (17) "Provisional license" means department approval to operate a rural medical center for a temporary period of time, issued to a person who is either not currently licensed by the department or certified by the federal government to provide one or more of the health care services that the person seeks to provide as a rural medical center.
- (18) "Rehabilitation agency" has the meaning given in 42 CFR 405.1702(i).
- (19) "Resident" means a person who receives nursing home services from a rural medical center.
- (20) "Rural health clinic" has the meaning given in 42 USC 1395x(aa)(2).
- (21) "Rural medical center" or "center" means an arrangement of facilities, equipment, services and personnel that is all of the following:
 - (a) Organized under a single governing and corporate structure.
 - (b) Capable of providing or assuring health care services, including appropriate referral, treatment and follow-up services, at one or more locations in a county, city, town or village with a population of less than 15,000 and that is in an area that is not an urbanized area as defined by the federal bureau of the census.
 - (c) A provider of at least 2 health care services under the arrangement or through a related corporate entity.

HFS 127.03 LICENSURE. (1) **LICENSE REQUIREMENT.** Only an entity that is licensed as a rural medical center by the department may establish, conduct, maintain, operate or permit to be maintained or operated, or represent and advertise by any means that it operates or provides rural medical center health care services.

(2) **APPLICATION.** (a) **Initial license.** An entity that meets the definition of rural medical center under s. HFS 127.02(23) may apply to the department for a license to operate as a rural medical center. Application shall be made on a form prescribed by the department and shall include all of the following information:

1. The name or names and address or addresses of the applicant who shall be a natural person or persons.

2. For all incorporated applicants, the date and state of incorporation, a copy of the articles of incorporation, tax status and, if an out-of-state corporation, evidence of authority to do business in Wisconsin.

3. The location of the center's central administrative offices, the location of the center's services and the locations of any branches of those services.

4. The names, principal business addresses and percentage of ownership interest of all officers, directors and stockholders owning 10% or more of stock and of all board members, partners and all other persons having authority or responsibility, directly or indirectly, for the operation of the services provided by the center, including owners of any business entity that owns any part of the land or buildings, and whether the interest is in the profits, land or buildings.

5. The identities of all creditors and lessors holding a security interest in the premises, whether land or buildings.

6. The names and addresses of persons serving on the center's board of directors.

7. In the case of a change in ownership, disclosure of any direct or indirect relationship or connection between the applicant and the prior manager, the prior owner and the manager of the rural medical center, and between the new owner and the manager of the rural medical center.

8. A detailed description of the geographic area to be served by the rural medical center.

9. Descriptions of the number and types of health care services to be provided by the rural medical center, and identification of all contracted health care services and the providers of those services, including the street address and distance of each provider from the rural medical center building.

10. Proof of sufficient financial resources to operate the center for at least 90 calendar days.

11. Any additional information requested by the department during the department's review of the license application.

Note: For a copy of the rural medical center license application form, write to the Provider Regulation and Quality Improvement Section, Bureau of Quality Assurance, P.O. Box 309, Madison, Wisconsin 53701-0309.

(b) License modification. A rural medical center proposing to add a new health care service shall apply to the department for a revised license. Application shall be on a form prescribed by the department and shall include all of the following information:

1. The name and address of the applicant.
2. Descriptions of the number and types of health care services to be provided by the rural medical center, and identification of all contracted health care services and the providers of those services, including the street address and distance of each provider from the rural medical center building.
3. Any additional information requested by the department during the department's review of the license application.

Note: For a copy of the form for adding a new health care service, write to the Provider Regulation and Quality Improvement Section, Bureau of Quality Assurance, P. O. Box 309, Madison, WI 53701-0309.

(3) **LICENSE FEES.** (a) An application for a license or for addition of a new health care service shall be accompanied by a license fee. Pursuant to s. 50.51(2)(c), Stats., the fee for a provisional license or for a regular license not preceded by a provisional license shall be the sum of fees for the specific types of health care services provided by the rural medical center as follows:

1. The fee for provision of hospital services shall be the same as the fee assessed under s. 50.135, Stats.
2. The fee for provision of nursing home services shall be the same as the fee assessed under s. 50.135, Stats.
3. The fee for provision of home health services shall be the same as the fee assessed under s. HSS 133.03(3) to (6).
4. The fee for provision of hospice services shall be the same as the fee assessed under s. HSS 131.14(6) and (7).

(b) The department shall determine an applicant's rural medical center license fee by adding the separate fees assessed for health care services under par. (a)1. to 4. The rural medical center license fee shall be assessed biennially, except that for a rural medical center that does not provide any of the health care services for which fees are assessed under par. (a)1. to 4., the rural medical center license fee shall be \$300 and shall be assessed for a two-year period.

(c) A rural medical center applying to initiate a new health care service shall pay a fee for the new service prorated for the period of time remaining until the next biennial license fee assessment, as determined by the department.

(4) REVIEW OF APPLICATION. (a) General provisions. The department shall perform a full review, an expedited review or a combined review of an application for a rural medical center license, depending on whether the applicant holds current, valid state licenses or approvals or federal certifications for the types of health care services described in the application.

(b) Review types. 1. 'Full review.' a. If the applicant proposes to provide health care services for which the applicant does not hold current, valid state licenses or approvals or federal certifications on the date of application for a rural medical center license, the department shall conduct an inspection under par. (c) and a review under par. (d).

b. If a rural medical center proposes to provide a health care service not currently listed on its license, the department shall conduct an inspection under par. (c) and a review under par. (d).

c. The department shall make a determination on the application within 90 calendar days after receiving the complete application.

2. 'Expedited review.' If the applicant proposes to provide health care services for which the applicant holds current, valid state licenses or approvals or federal certifications on the date of application for a rural medical center license, the department shall conduct a review under par. (d) and make a determination on the application within 30 calendar days after receiving a complete application.

3. 'Combined review.' If the application requires both full review and expedited review under this subsection, the department shall make a determination on the application within 90 calendar days after receiving a complete application.

(c) Inspection. Pursuant to s. 50.52(2)(b) to (c), Stats., the department may conduct an inspection of each of the health care services that the applicant proposes to provide, except that the department in lieu of conducting an inspection may accept evidence that for a specific type of health care service the applicant meets one of the following requirements:

1. Has current, valid state licensure or approval and is in good standing as described in par. (d)6. to operate as a hospital, a nursing home, a hospice or a home health agency applicable to the types of health care services that the applicant proposes to provide as a rural medical center.

2. Has a current, valid agreement and is in good standing as described in par. (d)6. to participate as an eligible provider in medicare for the types of health care services that the applicant proposes to provide as a rural medical center.

3. Is a critical access hospital in good standing as described in par. (d)6.

(d) Review criteria. The department shall review an application and make a determination on whether to issue a license based on all of the following criteria:

1. Whether the applicant has supplied all information required or requested by the department under sub. (2).

2. Whether the applicant proposes to provide health care services.

3. Whether the applicant qualifies as a rural medical center.

4. Whether the applicant is operating in compliance with the provisions of this chapter or is able to comply with the provisions of this chapter, as determined by the inspection under par. (c) where applicable.

5. For the proposed provision of hospice or nursing home services, whether the applicant is fit and qualified under s. HSS 131.14(3)(b) for hospice services or s. HFS 132.14(4)(b) for nursing home services.

6. Whether the applicant is in good standing. In making its determination of good standing, the department may review the information contained in the application and any other relevant documents, including but not limited to survey and complaint investigation findings for each health care services provider with which the applicant is or was affiliated during the past 5 years. The department shall also conduct a background check of the applicant as required by ch. HFS 12.. The department shall consider all of the following:

a. Any outstanding adverse action or state class "A" or "B" violations as defined by s. 50.04(4)(b)1. and 2., Stats., against the applicant.

b. The frequency of any noncompliance with state licensure or approval or federal certification laws in the applicant's operation of health care services in this or any other state.

c. Any conviction of the applicant for a crime related to the delivery of health care services or items, providing health care services without a license, controlled substances violations, neglect or abuse of patients or residents or assaultive behavior or wanton disregard for the health or safety of others. If the applicant is a corporation, the background check consideration applies to the chief executive officer, each officer or director of the corporation and each owner, directly or indirectly, of any equity security or other ownership interest in the corporation. This restriction does not apply if the corporation has terminated its relationship with the convicted administrator, officer, director or owner.

d. Any knowing or intentional failure or refusal by the applicant to disclose required ownership information.

e. Any prior financial failures of the applicant, including but not limited to those related to bankruptcy or to the closing of a health care services entity or the moving of its patients or residents.

(5) LICENSE ISSUANCE. (a) General provisions. 1. If the department approves an application following its review under sub. (4), the department shall issue either a provisional license under par. (c) or a regular license within the time period for the applicable type of review under sub. (4)(b), provided that the applicant pays the license fee under sub. (3).

2. The license shall bear the name and address of the rural medical center and the name and address of the applicant and identify the types of health care services that the center is licensed to provide.

3. The license shall state any applicable conditions and restrictions, including maximum bed capacity and the level of care that may be provided, and any other limitations that the department finds necessary and appropriate.

4. A license shall be issued exclusively for the rural medical center applicant named in the application and may not be transferred or assigned. A licensee shall fully comply with all requirements and restrictions of the license. When there is a change in the ownership of the rural medical center, the new operator shall submit a new application to the department.

5. Rural medical center licensees shall surrender to the department all single-service licenses or other approvals held for the types of health care services identified in the rural medical center license.

(b) Regular license. A regular license is valid until it is suspended or revoked.

(c) Provisional license. 1. If an approved applicant is not currently licensed by the department or certified by the federal government to provide one or more of the health care services that the applicant seeks to provide as a rural medical center, the department shall issue the applicant a provisional license.

2. A provisional license is valid for 6 months from the date of issuance per s. 50.52(4), Stats.

3. A rural medical center with a provisional license shall submit an application for a regular license to the department so that it is received by the department at least 45 calendar days before expiration of the provisional license. If an application for a regular license is not received by that date, the provisional license shall lapse as of the date of its expiration. If the department does not make a favorable determination under sub. (4) on the application for a regular license, the department may not issue a regular license. Expiration of a rural medical center's provisional license does not affect other licenses, approvals or certifications maintained by the entity.

(6) REPORTING OF CHANGES. (a) Changes requiring notice. 1. The licensee shall notify the department in writing of any changes that affect the continuing accuracy and completeness of the information required under sub. (2)(a). If the rural medical center provides nursing home services, any change in ownership shall be reported to the department in writing at least 30 calendar days prior to the change.

2. The licensee shall notify the department in writing of any changes in the administrator of the nursing home service within 2 business days of the change.

3. The licensee shall notify the department in writing of any changes in the director of nursing of the nursing home service within 2 business days of the change.

(b) Changes requiring new application. An application for a new license shall be submitted to the department within 30 calendar days after any of the following:

1. The licensee transfers title of the rural medical center, regardless of whether the transfer includes title to the real estate.

2. In a partnership, the removal, addition or substitution of an individual as a partner or the dissolving of an existing partnership and the creation of a new partnership.

3. The operator has relinquished management of the rural medical center.

(7) DENIAL, SUSPENSION OR REVOCATION. (a) Action. 1. 'Denial.' The department shall deny an application for an initial rural medical center license or for modification of a license to provide an additional health care service to any applicant not receiving a favorable license application determination under sub. (4) or failing to pay the license fee under sub. (3). The department shall provide written notice to the applicant within 45 calendar days after receipt of the complete application. If the department denies an application for a license or for authorization to provide a specific type of health care service for the sole reason that the applicant has an outstanding adverse action and the cause of the adverse action is subsequently corrected, the department shall issue the license within 30 calendar days after receiving notice from the applicant that the cause of the adverse action has been corrected, provided that the application is otherwise complete and the applicant pays the license fee under sub. (3).

2. 'Suspension or revocation.' a. Non-emergency. The department, after providing written notice to the licensee, may suspend or revoke a rural medical center license or authorization to provide a specific type of health care service if the department determines that the rural medical center has substantially failed to comply with the requirements of ss. 50.50 to 50.56, Stats., or this chapter. Except as provided in subd. 2.b., the department shall provide written notice to the licensee of the suspension or revocation at least 30 days before the suspension or revocation is to take effect.

b. Emergency. The department may, in the event of an emergency condition that imminently threatens the health, safety or welfare of rural medical center patients or residents, order summary suspension of new admissions to all or part of the rural medical center or order summary suspension of the rural medical center's authorization to provide a specific type of health care service until such time as the department decides that the rural medical center has removed or corrected the causes or violations creating the emergency.

(b) Contents of notice. In a notice of denial, suspension or revocation under par. (a), the department shall state the reasons for its action and specify the statute or rule and facts that constitute any violation or noncompliance. The notice shall identify the process under par. (g) for an appeal of the denial, suspension or revocation.

(c) Return receipt. If the department receives a return receipt for the notice sent under par. (a), the return receipt is conclusive evidence that the addressee received the notice. If the department does not receive a return receipt for the notice sent under par. (a), the addressee shall be presumed to have received the notice on the fifth calendar day after the date the notice was mailed.

(d) Effective date. 1. Subject to s. 227.51, Stats., a denial, suspension or revocation is effective on the date set by the department in the notice of denial, suspension or revocation, on the date of expiration of an existing license, except that:

a. In the event of a contested case hearing pursuant to s. 227.42, Stats., the effective date is the date of final action.

b. In the event of judicial review pursuant to s. 227.52, Stats., or a stay granted under s. 227.54, Stats., the effective date is the date of final action.

2. The department may delay the effective date of license revocation in order to permit orderly removal and relocation of patients or residents served by the rural medical center.

(f) Effect on other licenses, approvals, certifications or health care services. The department's denial, suspension or revocation of an application, license or authorization to provide a specific type of health care service shall have no bearing on any other license, approval or certification of health care services maintained in good standing as specified under sub. (4)(d)6., unless the applicant ceases to qualify as a rural medical center.

(g) Appeal of denial, suspension or revocation. An applicant or licensee may request a hearing under ch. 227, Stats., to appeal the department's decision to deny, suspend or revoke the application or license. The request for hearing shall be in writing and filed in the department of administration's division of hearings and appeals within 10 working days after receipt of the notice of denial under par. (a)1. or of suspension or revocation under par. (a)2. A request for a hearing is considered filed on the date of its receipt by the division of hearings and appeals. Review of the department's decision by that office is not available if the request for a hearing is received more than 10 working days after the date that the applicant or licensee receives the notice of denial, suspension or revocation of the license.

Note: A hearing request should be sent or may be delivered to the Department of Administration's Division of Hearings and Appeals, 5005 University Avenue, Suite 201, Madison, Wisconsin, 53705-5400.

HFS 127.04 COMPLIANCE WITH LAWS. All rural medical centers shall operate and provide health care services in compliance with all applicable federal, state and local government statutes, regulations, rules and ordinances and accepted standards and principles that apply to professionals providing health care services for the center.

HFS 127.05 INSPECTIONS AND INVESTIGATIONS. (1) The department may conduct an unannounced inspection of a rural medical center facility as often as required by the federal government or as the department deems necessary. The department may investigate complaints it receives concerning the operation of a rural medical center.

(2) (a) A rural medical center surveyed or investigated under this section shall provide the department with access to patient or resident health care records, regardless of the source of patient or resident health care payment, as well as clinical, financial and administrative records, throughout the duration of any survey, inspection or investigation that the department conducts.

(b) A rural medical center shall release patient or resident health care records without the informed consent of the patient or resident in response to a request by any federal or state governmental agency to perform a legally authorized function, including but not limited to management audits, financial audits, program monitoring and evaluation or facility licensure or certification.

(3) A survey or investigation by the department may include visits with patients or residents with the prior consent of the patients or residents. Upon the department's request, a rural medical center shall provide the department a list of names, addresses and other identifying information of current and past patients or residents. The department may select the names of the patients or residents to be visited and may visit those patients or residents with their prior consent.

(4) If a rural medical center interferes with or refuses to allow any survey, inspection or investigation under this section or s. HFS 127.06, the department may suspend or revoke the rural medical center's license.

HFS 127.06 CONSOLIDATED SURVEY REQUIREMENT. (1) Any survey by the department of a rural medical center shall be comprehensive and consolidated with all health care services listed on the license. In conducting a survey, the department shall select a sample of patients or residents served by the center to facilitate an outcome-based, program-wide consolidated survey.

(2) The department shall afford opportunities for representatives of the rural medical center to consult with department staff concerning compliance, noncompliance and findings throughout the duration of a survey.

HFS 127.07 VIOLATIONS AND PENALTIES. (1) **NOTICE OF VIOLATION.** Upon determining that a rural medical center is in violation of a requirement of this chapter, including any requirement under ss. HFS 127.15 to 127.24, the department shall promptly send a notice of violation to the chief executive officer, director, administrator or other designated agent of the rural medical center. The notice shall specify the rule violated and state the facts that constitute the violation. If the department receives a return receipt for the notice, the return receipt is conclusive evidence that the addressee received the notice. If the department does not receive a return receipt for the notice, the addressee shall be presumed to have received the notice on the fifth calendar day after the date the notice was mailed.

(2) **PLAN OF CORRECTION.** Within 10 calendar days of receipt of a notice of violation under sub. (1), the rural medical center shall submit a plan of correction to the department, detailing how the center plans to correct the violation or how the center has already corrected the violation. If the rural medical center fails to submit an acceptable plan of correction, the department may impose a plan with which the center shall comply. The department shall verify that the rural medical center has completed or complied with the plan of correction.

(3) **PROHIBITIONS.** No person may do any of the following:

(a) Intentionally prevent, interfere with or impede in any way the work of any duly authorized representative of the department in making investigations under this chapter or in enforcing this chapter.

(b) Intentionally retaliate or discriminate against any patient, resident or employee of a rural medical center for contacting or providing information to any state agency, as defined by s. 16.004(12)(a), Stats., or for initiating, participating in or testifying in an action to enforce any provision of this chapter.

(c) Intentionally destroy, change or modify the original report of an inspection that the department conducts under this chapter.

(d) Fail to correct, or attempt to interfere with the correction of, a violation within the maximum time for correction specified in a notice of violation or plan of correction, unless the department grants an extension and the rural medical center corrects the violation before expiration of the extension.

(e) Prevent or attempt to prevent any duly authorized representative of the department from examining any relevant accounts, books or records of the center in the conduct of official duties under this chapter.

(f) Prevent or attempt to prevent any duly authorized representative of the department from preserving evidence of any violation of any provision of this chapter.

(4) PENALTIES. As provided by s. 50.55(2), Stats., whoever violates sub. (3)(a), (b) or (c) may be imprisoned for up to 6 months or fined not more than \$1,000, or both, for each violation.

(5) FORFEITURES. The department may assess forfeitures in the manner prescribed by s. 50.55, Stats., against any person who violates any provision of this chapter except sub. (3)(a)(b) or (c).

(6) APPEAL. Except as provided by s. 50.55(1), Stats., a rural medical center that chooses to contest any department assessment under sub. (5) may request a hearing by sending, within 10 calendar days after receipt of a notice of assessment, a written request for hearing under ch. 227, Stats., to the department of administration's division of hearings and appeals.

Note: A hearing request should be sent or may be delivered to the Department of Administration's Division of Hearings and Appeals, 5005 University Avenue, Suite 201, Madison, Wisconsin, 53705-5400.

HFS 127.08 WAIVERS AND VARIANCES. (1) DEFINITIONS. In this section:

(a) "Variance" means the granting by the department of an alternative requirement in place of a nonstatutory requirement of this chapter.

(b) "Waiver" means the granting by the department of an exception from a nonstatutory requirement of this chapter.

(2) REQUIREMENTS FOR WAIVERS AND VARIANCES. The department may grant a waiver or variance if the department finds that:

(a) The waiver or variance will not adversely affect the health, safety or welfare of any rural medical center patient or resident.

(b) The requirement from which the rural medical center seeks relief would result in unreasonable hardship or is infeasible as applied to the rural medical center or a patient or resident of the rural medical center.

(c) If the request is for a variance, the proposed condition, method, procedure, practice, technique, equipment, personnel qualification, pilot project or other alternative is in the interests of the management of patient or resident care.

(3) PROCEDURES. (a) Requests. 1. A request for a waiver or variance shall be made in writing to the department and shall include all of the following:

a. The requirement from which the waiver or variance is requested.

b. The time period for which the waiver or variance is requested.

c. The reason or reasons for the request. The center shall provide an explanation of why the requirement from which the center seeks relief results in unreasonable hardship or is infeasible as applied to the rural medical center or a patient or resident of the rural medical center.

d. If the request is for a variance, the rural medical center's proposal of the alternative condition, method, procedure, practice, technique, equipment, personnel qualification, pilot project or other alternative is in the interests of the management of patient or resident care and is as protective as the requirement from which the waiver or variance is being sought.

2. A request for a waiver or variance may be made at any time.

3. The department may require additional information from the rural medical center before acting on the request.

Note: A request for a waiver or variance should be addressed to Provider Regulation and Quality Improvement Section, Bureau of Quality Assurance, P.O. Box 309, Madison, Wisconsin 53701-0309.

(b) Grants and denials. 1. The department shall grant or deny in writing each request for a waiver or variance. A notice of denial shall state the department's findings and reasons for denial and shall indicate that the rural medical center may request a hearing under par. (c). Except when additional information is requested under par. (a)3., if a notice of denial is not issued within 60 calendar days after the receipt of a complete request, the waiver or variance shall be automatically approved.

2. The department may limit the duration of any waiver or variance.

3. The department may impose conditions on a waiver or variance if the department finds that the conditions are necessary to protect the health, safety or welfare of rural medical center patients or residents.

4. The terms of a waiver or variance may be modified only upon written agreement between the department and the rural medical center.

(c) Appeal. 1. A rural medical center may contest the denial of a waiver or variance by requesting a hearing pursuant to ch. 227, Stats. The request for hearing shall be in writing and filed with the department of administration's division of hearings and appeals within 10 working days after receipt of the notice under par. (b). A request for a hearing is considered filed on the date of its receipt by that office.

2. The rural medical center shall bear the burden of proving by a preponderance of the evidence that a denial of a waiver or variance was unreasonable.

Note: A hearing request should be addressed or may be delivered to the Department of Administration's Division of Hearings and Appeals, 5005 University Avenue, Suite 201, Madison, Wisconsin, 53705-5400.

(d) Revocation. The department may revoke a waiver or variance, subject to appeal rights under par. (c), for any of the following reasons:

1. The department determines that the waiver or variance adversely affects the health, safety or welfare of the rural medical center's patients or residents.
2. The rural medical center failed to comply with the waiver or variance as granted or with a condition of the waiver or variance.
3. The person representing the rural medical center who received the waiver or variance notifies the department in writing that the center wishes to relinquish the waiver or variance and be subject to the requirement previously waived or varied.
4. Revocation is required by a change in state law.

SUBCHAPTER II - PROGRAM AND OPERATIONAL STANDARDS

HFS 127.16 NURSING HOME SERVICES. A rural medical center offering or proposing to offer nursing home services shall comply with ch. HFS 132 or 134, as appropriate, and 42 CFR 483, Subpart B. If ch. HFS 132 or 134 conflicts with this chapter, this chapter shall take precedence.

HFS 127.17 HOSPITAL SERVICES. A rural medical center offering or proposing to offer hospital services shall comply with ch. HFS 124 and 42 CFR 482. If ch. HFS 124 conflicts with this chapter, this chapter shall take precedence.

HFS 127.18 HOME HEALTH SERVICES. A rural medical center offering or proposing to offer home health services shall comply with ch. HSS 133 and 42 CFR 484. If ch. HSS 133 conflicts with this chapter, this chapter shall take precedence.

HFS 127.19 HOSPICE SERVICES. A rural medical center offering or proposing to offer hospice services shall comply with ch. HSS 131 and 42 CFR 418. If ch. HSS 131 conflicts with this chapter, this chapter shall take precedence.

HFS 127.20 CRITICAL ACCESS HOSPITAL SERVICES. A rural medical center offering or proposing to offer critical access hospital services shall comply with applicable sections of 42 CFR 400, 409, 410, 411, 412, 413, 424, 440, 485, 488, 489 and 498.

HFS 127.21 RURAL HEALTH CLINIC SERVICES. A rural medical center offering or proposing to offer rural health clinic services shall comply with applicable sections of 42 CFR 405, Subpart X and 42 CFR 491, Subpart A.

HFS 127.22 REHABILITATION, OUTPATIENT PHYSICAL THERAPY AND OUTPATIENT OCCUPATIONAL THERAPY SERVICES. A rural medical center offering or proposing to offer rehabilitation, outpatient physical therapy or outpatient occupational therapy services shall comply with applicable sections of 42 CFR 405 or 485.

HFS 127.23 AMBULATORY SURGERY CENTER SERVICES. A rural medical center offering or proposing to offer ambulatory surgery center services shall comply with applicable sections of 42 CFR 416.

HFS 127.24 END-STAGE RENAL DISEASE SERVICES. A rural medical center offering or proposing to offer end-stage renal disease services shall comply with applicable sections of 42 CFR 405, Subpart U.

The rules contained in this order shall take effect on the first day on the month following publication in the Wisconsin Administrative Register as provided in s. 227.22(2), Stats.

Wisconsin Department of Health and
Family Services

Dated:

By: _____
Joe Leean
Secretary

SEAL: